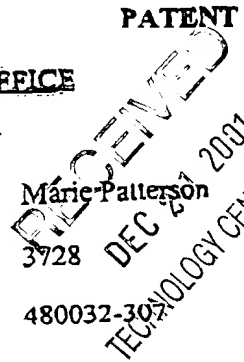


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Tracy E. Grim, et al. Examiner: Marie Patterson
Serial No. 09/592,462 Group Art Unit: 3728
Filed: June 9, 2000 Docket No. 480032-307
Title: FOOTGEAR WITH PRESSURE RELIEF ZONES



11
Declaration
6 pages
1/18/02

CERTIFICATE UNDER 37 C.F.R. 1.8
I hereby certify that this correspondence and identified enclosures are being deposited with the United States Postal Service, first class mail, postage prepaid, under 37 C.F.R. 1.8 on the date indicated, and is addressed to the Commissioner for Patents, BOX: Non-Fee Amendment, Washington, D.C. 20231 on _____

Justina S. Townsend

BOX: Non-Fee Amendment
Commissioner for Patents
Washington, D.C. 20231



SUPPLEMENTAL DECLARATION
OF TRACY E. GRIM

12-08-2001

U.S. Patent & TMO/TM Mail Rcpt Dt. #01

I, TRACY E. GRIM, hereby declare as follows:

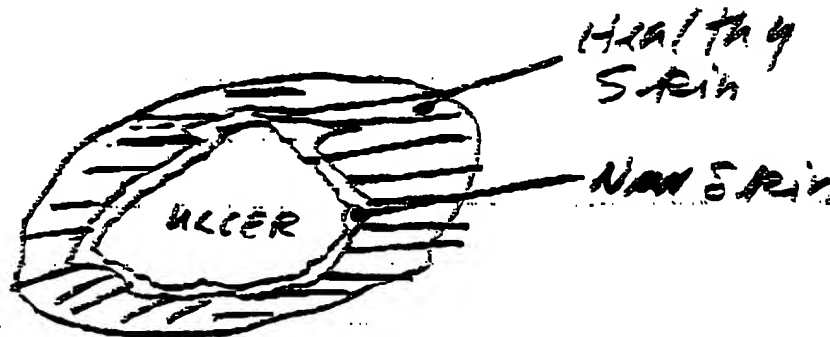
1. I hereby reaffirm the statements set forth in my prior Declaration in this case, dated September 10, 2001.
2. Concerning commercial success of the products within the scope of the claims presented in this application, sales since July 1997 to September 2001, have been in excess of \$5,900,000. This level of sales is considered to be unusually high for new products introduced by a relatively small company in the orthopaedic field; and the subject matter presented in the claims of the present application are believed to be a strong contributory factor for this unusually good commercial success.
3. With regard to the Kellermann U.S. Patent, it is first noted that it is primarily intended for use with "heel spurs and bunions (see col. 3, lines 37 and 38 for example). In order to obtain his desired result, Kellerman discloses a "very low friction upper surface"; and this is

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obtained by the use of a thin layer of "ultrahigh molecular weight polyethylene", or UHMW-PE, next to the skin, see the first full paragraph of column 5 of the patent.

4. Now, in contrast to the Kellerman focus on bone spurs and bunions, and the use of a stiff slippery surface for engagement by the foot, our structure is intended to provide full elimination of any pressure on ulcerated areas of the foot. If the stiff, low friction layer of Kellerman adjacent the foot as taught by Kellerman were used with relief areas cut through this layer, the ulcerated areas would soon become aggravated and enlarged by sliding engagement with the edges of the stiff slippery layer.

5. The recovery from ulcers on the feet of a diabetic patient, for example, is a slow, tedious process. Because the ulcer has very little blood supply and even less lymphatic return, ulcers on the feet tend to take months, sometimes years to heal. What happens is that the ulcerated area, if entirely free from pressure or frictional engagement, will slowly over a period of several weeks or months, grow an inwardly directed perimeter of new skin, which looks somewhat like this:



The growth of new skin is white in color, grows very slowly in cellular thicknesses and is very fragile. Any direct contact or rubbing involving the application of shear forces in the ulcerated area can tear the fragile cells and interrupt the slow growth process, and prevent healing.

6. Accordingly, if the foot engaging layer of Kellerman were to be used as the foot engaging layer of the Andrews patent, the foot of the patient would slide on the stiff, low friction layer, the ulcerated areas would impinge on the stiff edges of the upper layer, where the depressions are present, and healing would be interrupted and prevented.

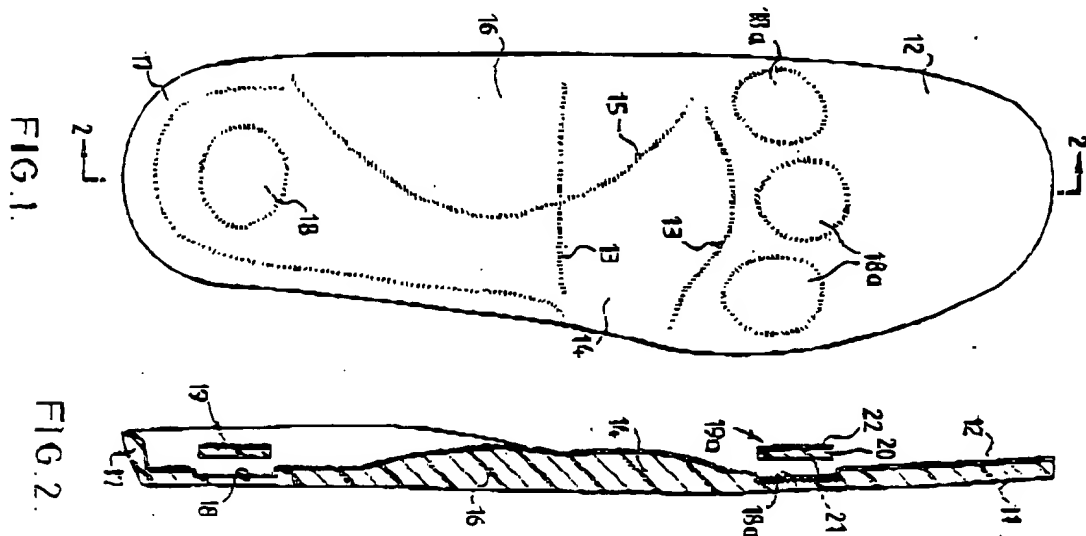
7. Concerning the Andrews patent, in the Office Actions, the following passage from the Andrews patent has been repeatedly quoted:

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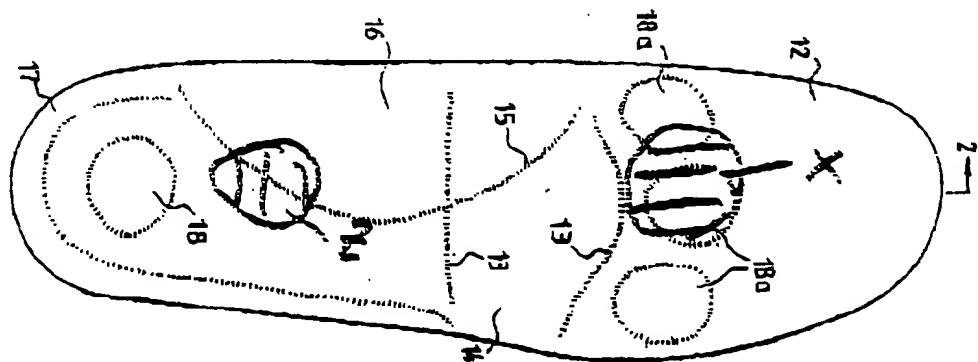
"the number shape and position of the depressions 18 and 18a may be chosen as best suited to the needs of most users".

However, it is respectfully noted that this passage clearly indicates that ~~there~~ will be a number of depressions; and accordingly there will necessarily be ridges between the depressions. Now we request that the following situation be actually considered:

(a) First, the Andrews insole is manufactured with depressions in selected areas, and necessarily ridges between the depressions, as follows:



(b) Now, consider the case where the same patient has the ulcer enlarged to extend over the area indicated at "X" below, or has a new ulcer develop at area "Z", shown below (which is common to diabetic patients having advanced bony deformation, called a "Charcot joint"):



What will the patient or his or her doctor do? Will they order a new specially made insole from the manufacturer? Or will they try to cut the existing insole to the new configuration? This dilemma clearly points up the shortcomings of the Andrews product.

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As noted above, the Andrews patent states that the number and position of depressions may be chosen as best suited to the needs of most patients. In accordance with this statement, the Andrews as manufactured will have depressions and will have intermediate raised portions. Accordingly, when the ulcerated areas underlie the raised portions, the patient and his or her doctor cannot readily handle the situation. The intermediate raised portions can start new ulcers because of focal pressure points.

This is the basic problem with the Andrews patent and product. It lacks flexibility and practicality. It is believed that this analysis indicates why the Andrews product is not seen on the market, while the assignee of the present invention has had nearly \$6,000,000 in sales in the last four years and two months.

8. It has been proposed in communications from the Patent Office that the Kellerman structure be combined with the Andrews structure. As noted above, Kellerman teaches the use of a high density, slippery thin, stiff layer in engagement with the foot or with a sock or stocking covering the foot. If such an upper surface were to be used with Andrews, and areas of the Andrews insole removed, the patient's foot would slide on the slippery surface and the edges of the depressions would abrade or injure the ulcerated areas. Alternatively if the concept of the lower relief areas of Kellerman were applied to Andrews device, the lower surface of the Andrews insole would be provided with removable elements, and the ulcerated areas of the patient's foot would not have the full relief needed for healing.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent application issuing thereon.

Respectfully submitted,

Date:

12/4/01

Tracy E. Grim

